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510(k) SUMMARY

As required by section 807.92(c)

Submitter	COUSIN BIOTECH 8 rue Abbe Bonpain F59117 WERVICQ SUD FRANCE
Contacts	Franck PELLETIER Regulatory Affairs Manager f.pelletier@cousin-biotech.com
Preparation date	02nd October, 2009
Trade Name	BIOMESH® CA.B.S.'Air® Composite
Common Name	POLYMERIC SURGICAL MESH
Classification Name	MESH SURGICAL POLYMERIC
Class	II
Product Code	FTL
CFR section	878.3300
Device panel	General & Plastic Surgery
Legally marketed predicate devices	BIOMESH® CA.B.S.'Air® Composite is compared to CABS'AIR (K072962) manufactured by COUSIN BIOTECH, INC and VENTRALEX HERNIA PATCH (K021736) manufactured by C.R. BARD, INC
Description	BIOMESH® CA.B.S.'Air® Composite medical devices are parietal prosthesis with inflatable expansion balloon and fixation threads.

Intended Use	BIOMESH® CA.B.S.'Air® Composite is intended for use in all forms of hernia repair requiring reinforcement with nonabsorbable support material.
Performance data	BIOMESH® CA.B.S.'Air® Composite conforms to the special control "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh".
Substantial equivalence	BIOMESH® CA.B.S.'Air® Composite has the same fundamental scientific technology, operating principle and intended use as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 25 2010

Cousin Biotech S.A.S.
% Mr. Franck Pelletier
Regulatory Affairs Manager
8 rue de l'Abbé Bonpain
Wervicq SUD 59117
France

Re: K093196
Trade/Device Name: BIOMESH® CA.B.S.'AIR® Composite
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL, OQL
Dated: June 18, 2010
Received: June 21, 2010

Dear Mr. Pelletier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K093196

Device Name: BIOMESH® CA.B.S.'Air® Composite

Indications for Use:

BIOMESH® CA.B.S.'Air® Composite is intended for use in all forms of hernia repair requiring reinforcement with nonabsorbable support material.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krone for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093196